REMARKS

Claims 25-30 and 33-37 are pending in the case and being examined. Claim 37 was found allowable.

Rejection Under 35 U.S.C. §112

Claims 25-28 and 33-35 stand rejected under section 112 (first paragraph) as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is believed by Applicants to be a rejection based on failure to meet the written description requirement.

The substance of the rejection appears to be that the specification does not identify which portion of the claimed polypeptide is identical to SEQ ID NO: 2 or 4 and reacts with anti-pneumococcal Sp36 antibody, nor indicates how specific the reaction between the antibody and the polypeptide needs to be. The specification is also stated to not disclose sequences having 75%, etc., identity to SEQ ID NO: 2 or 4 and which react with the antibody. Thus, the rejection is based on a requirement for more structure/function/activity details.

In response, Applicants contend that the application as filed fully supports the claimed invention. The Office Action concedes (at page 3, line 14) that Example 4 of the application describes reaction between group B and the indicated antibody to Sp36 as well as how this was measured. In addition, it is well known in the art how to generate polypeptides with amino acid substitutions, deletions, additions, etc., as well as how to measure cross-reactivity of a claimed polypeptide with an anti-Sp36 antibody. The argument that the application fails to provide specific sequences with the claimed

percent identities or to disclose what portions are identical with the disclosed sequences is believed to be inapplicable to the present claims because if numerous specific sequences were disclosed in the detail suggested by the office action then no functional limitation (i.e., binding to the antibody) would be needed.

In addition, Applicant believes that such a requirement is contrary to patent law and to the guidelines for the written description requirement. In support of this contention, Applicant invites the Examiner to review the guidelines regarding examination re the written description requirement, especially Example 14 thereof (called "product by function"). Applicant encloses herewith a copy of the relevant section (as downloaded from the PTO website). The sample claim therein was to a protein comprising the recited sequence or 95% identical thereto and which catalyzes reaction of A to form product B. The conclusion was that a rejection for failure to meet the written description requirement was not proper because the art of amino acid substitution was well known in the art and an assay for the enzyme activity was disclosed. More particularly, the guidelines note that the recited sequence was novel and unobvious, that the specific sequence was the only species actually disclosed and that the genus is sufficiently narrowed because all variants must exhibit the recited enzyme activity. No requirement was asserted for additional sequences or requiring identification of identical sequences between the protein variants. The guidelines then conclude that "one of skill in the art would conclude that Applicant was in possession of the necessary common attributes possessed by the members of the genus" and that "The disclosure meets the requirements of 35 U.S.C. §112 first paragraph as providing adequate written description for the claimed invention."

In the same way, the present application provides a specific sequence that is both novel and unobvious. Claim 25 recites an isolated polypeptide with at least 75% identity to the recited sequence and recites a specific antibody (anti-Sp36) for use in testing members of the claimed genus for their ability to cross-react with this antibody. It

is well known in the art how to make polypeptides with varying percent identities to the recited sequence and how to test for cross-reactivity using the disclosed anti-body. As with the example in the guidelines recited above the application provides a specific assay, along with identifying the specific antisera used in determining cross reactivity, thereby making the disclosure sufficiently definite to comply with section 112. In addition Applicants directed the Examiner's attention to Example 5 and the disclosure of Figure 2 where sequence alignments of the disclosed homologs with Sp36 are shown, thereby facilitating the identification of highly conserved and/or homologous regions between these polypeptides.

In the interests of clarifying the claims, Applicants have amended claim 25 to recite that the claimed isolated polypeptide binds to an antibody specific for Sp36 (whose sequence is shown in Figure 2 and which was previously added to the Sequence Listing as SEQ ID NO: 7). Claims 28 and 33 have been likewise amended.

Additional References

Applicant includes herewith a copy of the International Search Report for PCT/US00/23417, which is the corresponding international application, along with copies of the 4 references cited therein. Applicant believes that these references do not render the claims unpatentable for the following reasons:

1. WO 98/18930 – this publication merely discloses the Sp36 protein, which is already disclosed in the application as filed. The International Search Authority applied SEQ ID NO: 55 (Sp36) at page 59 of this reference to original claim 8 because that claim recited a polypeptide with at least 25% identity to Sp36 and so the sequence in the reference had 100% (at least 25%) identity but that ignored the limitation imported from original claim 1 that the polypeptide have at least 75% identity to SEQ ID NO: 2, 4

or 6. Thus, original claim 8 could not have encompassed Sp36 itself because of the low percent identities given in Table 1 of the application. Thus, this references in not applicable to the claims currently pending or to the originally filed claims.

2. Spellerberg et al has already been dealt with in the present prosecution and is no longer in issue. This reference was first cited by the Examiner in an Office Action dated 3 April 2001 (Paper No. 7), only a few months after the International Search Report was issued. Applicant has not submitted a copy of this reference.

3. WO 99/42588 was published 26 August 1999 whereas the present application claims priority to U.S. Provisional Application 60/150,750, filed 25 August 1999, thereby predating the reference so that the latter is not prior art.

4. WO 00/06736 was published 10 February 2000, well after the priority date of the present application and thus is not prior art.

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